DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

01-PHI-17

WARNING LETTER

May 7, 2001

FEDERAL EXPRESS

Richard Garman
President/CEO
Wayne Memorial Hospital
601 Park Street
Honesdale, PA 18405

Re: Inspection ID: 1459530009

Dear Mr. Garman:

We are writing to you because on April 23, 2001, your mammography facility located at **Pike County Medical Center, HC8 Box 8445, Hawley, PA 18428**, was inspected by a representative from the Commonwealth of Pennsylvania, acting in behalf of the Food and Drug Administration (FDA). Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

This inspection revealed the following level 1 and level 2 noncompliances:

Level 1 Inspection Finding:

Quality Standards – Equipment: Daily Quality Control Tests **[21 CFR 900.12(e)(1)]**
- Use of Test Results **[21 CFR 900.12(e)(8)(ii)(A)]**

".....A processor performance test shall be performed on each day that clinical films are processed for that day...(ii) The mid-density shall be within +/- 0.15 of the established operating level....(iii) The density difference shall be within +/- 0.15 of the established operating level."

"If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:.... Before any further examinations are performed or any films are processed using a component of the mammography system that failed.....".

OBSERVATION: Mammograms were processed in th[redacted]processor when it was out of limits on at least 5 days.

Level 2 Inspection Findings:

Quality Standards – Infection Control **[21 CFR 900.12(e)(13)]**

"Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and ....."

OBSERVATION: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.

Your written procedure for infection control was not complete in that it did not specify the procedure for documenting that infection control procedures were implemented when the mammography equipment came in contact with blood or other potentially infectious materials.

Quality Standards – Equipment: Weekly Quality Control Tests **[21 CFR 900.12(e)(2)]**
- Use of Test Results - **[21 CFR 900.12(e)(8)(ii)(A)]**

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly. (i)....(ii)....(iii) The phantom image shall achieve at least the minimum score established by the accreditation body.....(iv) The density difference.... shall not vary by more than ±0.05 from the established operating level."

"If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:.... Before any further examinations are performed or any films are processed using a component of the mammography system that failed....."

OBSERVATION: Corrective action before further exams, for a failing image score, or a phantom background optical density or density outside the allowable regulatory limits was not documented for the [redacted] mammography unit.

Review of the phantom QC records for the [redacted] mammography unit found that the density difference exceeded the established operating limit by more than [redacted] on 9/29/2000, 10/19/2000, and 1/26/2001. Patient exams were performed during the weeks of these phantom images. Corrective action was not taken before further exams in each of the above failed test results.

Quality Standards – Personnel: Radiologic Technologists – Continuing Education [21 CFR 900.12(a)(2)(iii)]

".... the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two....".

OBSERVATION: Failed to produce documents verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36-months.

The facility only had documentation of [redacted] CEU's in mammography for [redacted]

Quality Standards – Medical Records and Mammography Reports: Contents and Terminology **[21 CFR 900.12(c)(1)(iv)]**

"Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:....Overall final assessment of findings, classified in one of the following categories....."

OBSERVATION: [redacted] of [redacted] random reports reviewed did not contain an assessment category.

Review of [redacted] of [redacted] medical reports found that incorrect wording was being used for your category [redacted] and category [redacted] exams. The wording of "[redacted] is not acceptable for the category [redacted] type exams. The wording of "[redacted] is not acceptable for the category [redacted] type exams. Also, it was observed that exams diagnosed requesting ultrasound followup are incorrectly given an assessment category III classification. Exams which indicate that ultrasound exam is recommended should be given an assessment of "Incomplete: Needs additional imaging evaluation".

Level 3 Inspection Finding:

Quality Assurance – General **[21 CFR 900.12(d)]**

"Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility."

OBSERVATION: The QA program is inadequate for missing or incomplete QC test procedures.

The QC test procedures for performing the phantom image test and the other required QC tests are not adequate since they are not written in a manner to ensure the accuracy and reliability of the test results.

Quality Standards – Personnel: Retention of Personnel Records **[21 CFR 900.12(a)(4)]**

"Facilities shall maintain records to document the qualifications of all personnel....These records must be available for review by the MQSA inspectors."

OBSERVATION: The required personnel qualification documents were unavailable during the inspection.

Complete personnel qualification documents were not available for [redacted] RT, and the medical physicist, [redacted]

The specific problems noted above appear on the attached revised MQSA Facility Inspection Report with a print date of April 30, 2001. The original report issued to the facility on April 24, 2001 was modified to remove two level 2 noncompliance regarding the qualifications of your medical physicist based on information faxed to the FDA on April 26, 2001. Because these conditions may be symptomatic of serious underlying problems that could

compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to:

- placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring,
- assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards,
- suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

It is necessary for you to act on this matter immediately. Please address the following items in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- provide a copy of your written procedure for issuing lay letters that specifies that all patients will receive a lay letter and the time frames for when these letters must be sent for each type of lay letter. Also send sample copies of each lay letter, including the lay letter to be sent to patients with exams given an assessment category of "Incomplete: Needs additional imaging evaluation".
- provide a copy of your written procedure for performing the phantom QC test which includes the criteria for a passing phantom image and procedures for taking and documenting corrective action when the phantom QC test fails for any of the required parameters.
- provide a copy of your revised written infection control procedure which includes the requirement to log or chart when infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials.
- provide documentation showing that the radiologic technologist [redacted] has met the continuing education requirement of 15 CEU's in mammography in a 36-month period; or steps taken to remove [redacted] from performing independent mammography exams until the 15 CEU requirement is met.
- provide a copy of your procedure for assigning assessment categories to each medical report and the wording to be used for each category, and example copies of medical reports for each of the six assessment categories.
- provide copies of your written procedures for performing the required QC test procedures that provide specific instructions on performing each test and the reference source for the procedure.
- provide a copy of your written procedure which describes the documents that must be maintained for each interpreting physician, radiologic technologist, and medical physicist.

Please submit your response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

With a copy to:

David Gaisior
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Lee Park, Suite 6010
555 North Lane
Conshohocken, PA 19428

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,

Cynthia J. Rabastro

for Thomas Gardine
District Director
Philadelphia District

Attachment: Revised MQSA Facility Inspection Report: Print Date 4/30/2001
Inspection ID: 1440140006

cc: Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

David Gaisior
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Lee Park, Suite 6010
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